DETAILED ACTION

Election/Restrictions

1. Claims 3-5, 7, 8, 10, 16, 19, 20, 23, 24, and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 18 September 2006.

2. The amendment of 10 May 2011 included the addition of new claims 34-37, with claim 34 being independent and claims 35-37 depending therefrom. The method of claim 34 is drawn simply to "[a] method of performing energy transfer" and as such, does not require, much less result in, any analysis of binding between a sensor polynucleotide binding protein and a target polynucleotide, which the elected invention is drawn to. Accordingly, claims 34-37 are deemed to be drawn to a different invention and have been withdrawn from consideration.

Drawings

3. The drawings were received on 10 May 2011. These drawings are acceptable.

Claim Rejections - 35 USC § 112

4. Claims 1, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

5. Attention is directed to MPEP 904.01.

> The breadth of the claims in the application should always be carefully noted; that is, the examiner should be fully aware of what the claims do not call for, as well as what they do require. During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See *In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997). See MPEP § 2111 - § 2116.01 for case law pertinent to claim analysis.

6. It is noted with particularity that narrowing limitations found in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. *In re Philips Industries v. State Stove & Mfg. Co, Inc.*, 186 USPQ 458 (CA6 1975). While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into the claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992).

7. Claims 1 and 33 are each independent, are all under consideration, and, for convenience, are reproduced below.

1. (Currently Amended) An energy transfer assay method for analyzing binding of a sensor polynucleotide binding protein to a target polynucleotide comprising:

providing a sample that is suspected of containing a target polynucleotide;

providing a ~~polycationic multichromophore~~ conjugated polymer that interacts with the target polynucleotide and upon excitation is capable of transferring energy to a signaling chromophore;

providing a sensor polynucleotide binding protein (PBP) that can bind to the target polynucleotide, said sensor PBP conjugated to the signaling chromophore;

contacting the sample with the sensor PBP and the ~~multichromophore~~ conjugated polymer in a solution under conditions in which the sensor PBP can bind to the target polynucleotide, if present;

applying a light source that can excite the ~~multichromophore~~conjugated polymer; and

detecting whether light is emitted from the signaling chromophore, thereby indicating binding of the sensor polynucleotide binding protein to the target polynucleotide.

33. (Currently Amended) An energy transfer assay method for analyzing binding of a sensor polynucleotide binding protein to a target polynucleotide comprising:

providing a sample that is suspected of containing a target polynucleotide;

providing a ~~polycationic multichromophore~~ conjugated polymer that interacts with the target polynucleotide and upon excitation is capable of transferring energy to a signaling chromophore;

providing a sensor polynucleotide binding protein (PBP) that can bind to the target polynucleotide, said sensor PBP conjugated to the signaling chromophore;

contacting the sample with the sensor PBP and the ~~multichromophore~~ conjugated polymer in a solution under conditions in which the sensor PBP can preferentially bind to the target polynucleotide, if present;

applying a light source that can excite the multichromophoreconjugated polymer; and

detecting whether light is emitted from the signaling chromophore, thereby indicating binding of the sensor polynucleotide binding protein to the target polynucleotide.

8. In accordance with claim 1, one need only contact "the sample with the sensor PBP and the conjugated polymer in a solution under conditions in which the sensor PBP can bind to the

target polynucleotide." The "conditions" are not required to be such that binding only occurs between the PBP and the target polynucleotide. Rather, they have been construed as encompassing conditions where non-specific binding can occur. Given such, it would be impossible to definitiely analyze the "binding of a sensor polynucleotide binding protein to a target polynucleotide," as is required of the preamble of claim 1. In short, the claimed method is deemed to be inoperable.

9. Dependent claim 12 further limits claim 1 to those conditions where "the sample is contacted with the sensor PBP and the conjugated polymer in the presence of a sufficient amount of an organic solvent to decrease hydrophobic interactions between the sensor PBP and the conjugated polymer." Givent that claim 12 must furher limit claim 1 from which it depends, claim 1 must encompass conditions where no "suffficient amount of an organic solvent" is used as as such, hydrophobic interactions between the sensor PBP and the (non-specifically formed) "cojugated polymer" can proceed at will. The specification has not been found to enable the full scope of claim 1 in thtis regad. To the extent that claims 9, 13-15, 17, 18, 21, 22, 27, 28, and 30-32 all depend from claim 1, and do not recite the limitations of claim 12, they too have been construed as allowing for the increased formation of hydrophobic interactiotns between the sensor PBP and non-specific conjugated polymers.

10. Claim 33, like claim 1, leaves open the "conditions" to encompass non-specific binding between the PBP and the target polynucleotide. While claim 33 does recite that the "conditions" are such that "the sensor PBP can preferentially bind to the target polynucleotide, if present," such does not exclude formation of non-specific binding products for which a detectable signal

can result irrespective of any target polynucleotide actually being present. Accordimngly, the method of calim 33 is deemed to be inoperable.

11. The preamble of claims 1 and 33 clearly states that the method is for "analyzing binding of a sensor polynucleotide binding protein to a target ppolynucletoide." The method does not appear to actually result in their requisite analysis. Claim 1 culminates with the step of: "detecting whether light is emitted from the signaling chromophore, thereby indicating binding of the sensor polynucleotide binding protein to the target polynucleotide." While the methd step may provide for an indication of binding having taken place, it is not an analysis of the binding, which the method is required to be direced to. In short, the method as claimed, is deemed to be inopereble.

12. Given that it is not possible to satisfy the enablement requirement for a emthod that is inoperable, claims 1, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

13. Claims 1, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-37 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well-established utility.

14. Independent claims 1 and 33 are each drawn to a method of "analyzing binding of a sensor polynucleotide binding protein to a target polynucleotide." While the recited method steps are to result in a determination of whether or not a target polynucleotide is present, such is not the stated objective of the claimed method. Rather, one is to be analyzing the binding of the

PBP to the target. The target is not required to have any utility and the resultant analysis, should the method actually recite method steps for such analysis, is not required to produce any information that is deemed to have a specific, substantial and credible asserted utility.

15. Claims 1, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-37 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 1, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

18. Claims 1, 12-15, 17, 18, 21, 22, 27, 28, and 30-33 are indefintie with respect to what constitues the metes and bounds of "conjugated polymer." A review of the disclosrure fails to find where a limiting definition of the expression is provided.

19. Claims 1, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are those that result in the analysis of the binding of a PBP to a target nucleic acid. As presently worded, the claimed

method results in the determination of whether or not the PBP has bound to a target nucleic acid, which is not the same as analyzing the binding of a PBP to a target nucleic acid, which presupposes that the PBP has already bound to the target polynucleotide.

Claim Rejections - 35 USC § 101

20. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

21. Claims 1, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-33 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

22. In accordance with claim 1, one need only contact "the sample with the sensor PBP and the conjugated polymer in a solution under conditions in which the sensor PBP can bind to the target polynucleotide." The "conditions" are not required to be such that binding only occurs between the PBP and the target polynucleotide. Rather, they have been construed as encompassing conditions where non-specific binding can occur. Given such, it would be impossible to definitiely analyze the "binding of a sensor polynucleotide binding protein to a target polynucleotide," as is required of the preamble of claim 1. In short, the claimed method is deemed to be inoperable.

23. Claim 33, like claim 1, leaves open the "conditions" to encompass non-specific binding between the PBP and the target polynucleotide. While claim 33 does recite that the "conditions" are such that "the sensor PBP can preferentially bind to the target polynucleotide, if present," such does not exclude formation of non-specific binding products for which a detectable signal

can result irrespective of any target polynucleotide actually being present. Accordimngly, the method of calim 33 is deemed to be inoperable.

24. The preamble of claims 1 and 33 clearly states that the method is for "analyzing binding of a sensor polynucleotide binding protein to a target ppolynucletoide." The method does not appear to actually result in their requisite analysis. Claim 1 culminates with the step of: "detecting whether light is emitted from the signaling chromophore, thereby indicating binding of the sensor polynucleotide binding protein to the target polynucleotide." While the methd step may provide for an indication of binding having taken place, it is not an analysis of the binding, which the method is required to be direced to. In short, the method as claimed, is deemed to be inopereble.

25. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-33 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

Conclusion

26. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571)272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634